Effect of Health games on Cognitive Function in Parkinson’s Disease

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON21375

Source
NTR

Health condition

mild cognitive impairment

Sponsors and support

Primary sponsor: University Medical Centre Maastricht
Source(s) of monetary or material Support: University Medical Centre Maastricht

Intervention

Outcome measures

Primary outcome

cognition as measured by a standard neuropsychological assessment and online assessment

Secondary outcome

Compliance will be registered during the trial. This includes duration of playtime and whether or not subjects continue playing the game after 12 weeks.

MDS-UPDRS is used to score motor functions: speech, facial expression, tremor at rest, rigidity, hand movements, posture, gait, etc.

Several non-motor symptoms:

- depression (HADS),

- a self-report evaluation of perception, memory and motor-function in daily life (CFQ),

- functional abnormalities associated to cognitive impairment (PD-CFR),

- functional disability (pre-R-ODS),

- quality of life (PDF-39),

- impulsive behavior (BIS-11).

Biological endpoints (fMRI): change in the activity of the resting-state network associated with executive function that covers several medial-frontal areas, including the anterior cingulate, paracingulate and occipital cortex.

Study description

Background summary

Cognitive impairment is an important non-motor symptom in PD and major determinant of the quality of life. The study aims to evaluate the effects of a versatile web-based health game on cognition and compliance in Parkinson’s disease with mild cognitive impairment.

Study objective

To evaluate the effects of a versatile web-based health game on cognition and compliance in Parkinson’s disease with mild cognitive impairment.

Study design

baseline: t=0

12 weeks: t=1

24 weeks: t=2

Cognition is measured on all timepoints by calculating a z-score on a standard neuropsychological assessment and several self report questionnaires (HADS, CFQ, PD-CFR, Pre-R-ODS, PDQ39, and BIS-11).

Compliance is measured on all timepoints.

Motor symptoms are measured on all timepoints using the UPDRS-PD part III (motor symptoms).

Biological entpoints are measured on t=0 and t=1 in a subgroup of 40 participants using functional magnetic resonance imaging (fMRI).

Intervention

The intervention group receives a computerized cognitive training (health game) for a first period of 12 weeks. During this first period, the control group is placed on a waiting list. At the start of the second period of 12 weeks, both the intervention and the control group are allowed to receive the cognitive training.

Contacts

Public
Oxfordlaan 10

M. Kuijf
PO box 5800

Maastricht 6202 AZ
The Netherlands
Phone. 043 38 77056
Scientific
Oxfordlaan 10

M. Kuijf
PO box 5800

Maastricht 6202 AZ
The Netherlands
Phone. 043 38 77056

Eligibility criteria

Inclusion criteria

Diagnosis of idiopathic PD according to the UK Brain Bank Criteria,

Cognitive impairment at baseline in line with the Level 1 criteria for MCI and a cutoff of 1.5 SD below the normative mean,
Aged between 40 and 75 years old,

Not receiving any other cognitive therapy or intensified physical activity during the study,

Stable dopaminergic medication within last 3 months.

Exclusion criteria

Hoehn & Yahr stage 4 or 5,

Advanced problems in cognitive functioning: Montreal Cognitive Assessment (MoCa) < 21/30,

Habitual gamers (>1hr games/week in preceding year),

Active depression or psychosis and/or treatment with antidepressant or antipsychotic drugs,

Medication interfering with cognition including anticholinergic medication, benzodiazepines not used as sleep medication and stimulants (i.e. methylphenidate),

Premorbid intelligence < 86 based on the Dutch National Adult Reading test (NART),

Severe auditory or visual deficits,

History of active thyroid disease, stroke with residual deficits, severe hypertension or diabetes or head trauma interfering in cognition,

Excessive daytime sleepiness (Epworth Sleepiness Scale score >10),

(MRI substudy exclusion: any piece of metal in the body, and/or claustrophobia).

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2016
Enrollment:	222
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL5502

Register	ID
NTR-old	NTR5637
Other	MEC/IRB Maastricht : 141128

Study results